Microsampling for therapeutic drug monitoring of imatinib, dasatinib, nilotinib, gilteritinib, midostaurin, and venetoclax

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Ethical review	Approved WMO
Status	Pending
Health condition type	Leukaemias
Study type	Interventional

Summary

ID

NL-OMON57005

Source
ToetsingOnline

Brief title
Microsampling Oral Oncolytics

Condition

- Leukaemias
- Miscellaneous and site unspecified neoplasms benign

Synonym
leukaemia; gastrointestinal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Afdelingsfonds KFT

Intervention

Keyword: Microsampling, Oncolytics, TDM, TKI

Outcome measures

Primary outcome

The primary endpoint is the method agreement between plasma and microsampling (DBS/VAMS). The secondary endpoints are the success rate of microsampling and the difference in SUS score between HemaXis DB 10 and Mitra Clamshell.

Secondary outcome

• Success rate of microsampling: calculated by the percentage of DBS/VAMS spots that was accepted for analysis by the laboratory technician. Reasons for disapproval will be described by the laboratory technician .

• SUS score: calculated by converting the questionnaire into a 0 to 100 scale score. In the SUS scale, *strongly disagree* correlates with 1 point, *disagree* with 2 points, *neutral* with 3 points, *agree* with 4 points and *strongly agree* with five points. The SUS score equals to (X + Y) x 2.5. X is the sum of the points for all odd-numbered questions minus 5. Y is 25 minus the sum of all even-numbered questions.

Study description

Background summary

Orally administered oncolytics are characterised by high interpatient

variability in pharmacokinetics. Individual patients are therefore potentially at risk to receive either subtherapeutic or supratherapeutic treatment. Therapeutic drug monitoring (TDM) is a well-established method for personalized dosing of drugs, and has become part of standard of care in medical and hemato-oncology when treating patients with a number of frequently used oral oncolytics, e.g. imatinib, dasatinib, and nilotinib. Currently, blood sampling is performed at the hospital. Dried blood spot microsampling of oral oncolytics offers a home based alternative with multiple benefits. It could reduce the burden of hospital visits for blood sampling. Additionally, it offers the opportunity to move from dose recommendation based on trough concentrations (Ctrough) to recommendations based on Area Under the concentration versus time Curve (AUC). However, clinical validation and implementations studies for microsampling are warranted.

Study objective

The primary objective is to perform a clinical validation of dried blood spot microsampling of imatinib, dasatinib, nilotinib, gilteritinib, midostaurin, and venetoclax. The secondary objective is to test the feasibility of home monitoring (microsampling TDM) of these drugs in oncology and hemato-oncology patients.

Study design

A single center prospective clinical validation study.

Intervention

Patients will be asked to provide twelve microsampling samples obtained by finger prick (eight dried microsampling spots and four wet blood samples in microtainer EDTA) and four plasma samples obtained by venepuncture. The paired samples have to be obtained within 5 minutes of each other. Sampling will take place before the ingestion of the oral oncolytic (trough concentration, Ctrough) and every hour up to three hours after drug administration (C1, C2 and C3). Microsampling collection will be performed using two different sampling devices, HemaXis DB 10 and the Mitra Clamshell. Patients will be assisted by a nurse practitioner with the sampling of the first spot, and the sampling of the remaining spots will be performed by the patient. In order to evaluate the feasibility of at home microsampling with both sampling devices, patients will receive two kits for home use of both HemaXis DB 10 and Mitra Clamshell. Patients will be asked to perform four blood trough concentrations at home, two with every device. After obtaining the fourth sample, patients will be asked to send the samples by regular mail to the laboratory. In order to evaluate the user-friendliness of both microsampling devices, patients will be asked to fill the System Usability Scale (SUS).

Study burden and risks

Patients will be asked to perform the blood sampling while in the hospital for regular blood sampling. The remainder of sampling shall be performed at home to decrease the burden. Since the only invasive procedure is venepuncture and microsampling finger prick, the risk of adverse events is very low. No effect is expected on treatment outcome as results of the microsampling will not be available to inform treatment. The risk of participating in this trial is very low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all

of the following criteria:
• Willing and able to provide informed consent;
• 18 years of age or older;
• Using one of the following drugs:
o Imatinib
o Dasatinib
o Nilotinib
o Gilteritinib
o Midostaurin
o Venetoclax

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Not able to sample themselves using a finger prick.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2024
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-09-2024

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	24-01-2025
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86162.058.24